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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/790,544

03/01/2004

Miroslav Colic

4904-4DIV

9685

7590 10/18/2007
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EXAMINER

XIE, XIAOZHEN

ART UNIT	PAPER NUMBER
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1646

MAIL DATE	DELIVERY MODE
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10/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/790,544

Applicant(s)

COLIC, MIROSLAV

Examiner

Xiaozhen Xie

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 30 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-23 is/are pending in the application.
- 4a) Of the above claim(s) 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-19 and 21-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Applicant's amendments of the specification and the claims received on 30 July 2007 have been entered.

Claims 1-14 have been cancelled. Claims 15-23 are pending. Claim 20 is withdrawn from further consideration as being drawn to a nonelected species. Claims 15-19 and 21-23 are under examination to the extent they read on the elected species (i.e., the pharmaceutical composition further comprises pro-oxidant metal complexes and a cytokine which is IL-12).

Specification

The objection to the specification is maintained because Applicant's amendment of the specification received on 30 July 2007 fails to update the status of the related applications. Application No: 09/640,218 is abandoned. The first line of the specification should include updated cross-reference to related applications.

Claim Objections Withdrawn

The objection to claim 21 for a typographical error is withdrawn in response to Applicant's amendment of the claim.

Claim Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-19 and 21-23 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a lung cancer and a colorectal cancer in a patient comprising administering to the patient a pharmaceutical composition comprising a zeolite that has a mean particle size of 250 nm, does not reasonably provide enablement for treating any type of cancer, nor by administering zeolite of any sizes. The basis of this rejection is set forth at pp. 4-6 of the previous Office Action.

Applicant argues that based on the examples set forth in the specification, one skilled in the art would be able to practice the invention with other types of cancer and other sizes of zeolites.

Applicants' argument has been fully considered but has not been found to be persuasive.

The previous office action (26 January 2007) has set forth the reasons why one skilled in the art would not be able to practice the invention as broadly claimed based on the disclosure and examples of the specification, as well as the state of the art. Applicant, however, does not indicate where in the specification, e.g., in which example(s), Applicant has provided detailed guidance to treat any type of cancer by administering (e.g., by injecting) any type of zeolite. As stated previously, Applicant has disclosed three different uses of the nano-engineered zeolite, (e.g., clinoptilolite with a mean particle size of 250 nm): 1) the nano-engineered zeolite can be used to

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encapsulate metal complexes that act as antioxidants or prooxidants (catalytic salen-metal antioxidants or prooxidants with cobalt, manganese, iron, rhodium and palladium) (Example I), and exhibit anti-cancer activity in culture cells and in animal tests using lung, colorectal, breast and melanoma cancer models (Example IV). In such case, tissues or cells need in direct contact with the nano-engineered catalytic salen-metal antioxidants encapsulated zeolite; 2) Clinoptilolite with a mean particle size of 250 nm can be used as a vaccine adjuvant to enhance the immunogenicity of proteins, cell parts or whole cell vaccines. In such case, the clinoptilolite was injected near the tumor site to attract lymphocytes, and significant infiltration of lymphocytes and tumor remission were observed with melanoma, adenocarcinomas of lung and colorectal models (Example VII); and 3) The specification also teaches that the zeolite can be used to incorporate small drugs, macromolecules or whole cells for a delayed sustained release. Applicant, however, has not provided guidance to treat other types of cancer, for example, a non-tumor type of cancer such as leukemia, or an inoperable brain tumor wherein injection of the zeolite to the tumor site is impossible. As for the particle sizes of zeolites, the state of art teaches that zeolites are mostly used in industrial applications as catalysts, ion-exchangers, adsorbents, and detergent builders. Because larger particles (e.g., >5 microns) sediment from a suspension, and impose the risk of side effects, they obviously are not suitable for injection into an animal or human body.

Therefore, without detailed guidance or working example from the specification, the artisan would not know how to practice the invention as broadly claimed without undue experimentation. The scope of patent protection sought by Applicant as defined

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by the claims fails to correlate reasonably with the scope of enabling disclosure set forth in the specification.

Conclusion

NO CLAIM IS ALLOWED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Xiaozhen Xie, Ph.D.
October 3, 2007

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646